

Remarks

Applicant respectfully requests reconsideration and allowance of this application in view of the amendments above and the following comments. Applicants respectfully submit that the amendments are fairly based on the specification and respectfully request their entry. A copy of the marked up claims showing the amendments, as well as a clean copy of the claims encompassing the amendments, is attached hereto.

Main claim 1, has been amended above to clarify the language of the method and to clearly set forth that each sample contains a single compound to be tested and that all reaction vessels have identical reagents added to them. Thus, the concept of many identifiable samples in one assay, as embodied in Applicant's claimed method, is now more readily apparent. Claims 2, 4 and 10 have been cancelled above and limitations therefrom have been incorporated into claim 1. The amendments to the claims are discussed in further detail, in the responses to the rejections below.

35 U.S.C. § 112, SECOND PARAGRAPH REJECTION OF CLAIMS 1-11

Claims 1-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner objects to what is viewed as vague and confusing language and informalities within the claims, such as lack of antecedent basis. Applicant respectfully traverses this rejection for the reasons set forth below.

Regarding the above rejection as applied to claim 1, step b), with respect to the phrase “dispensing each of the N populations of carrier beads into a separate corresponding one of N different reaction vessels” and its perceived ambiguous meaning, Applicant points out that the phrase has been amended above. Applicant gratefully acknowledges the Examiner’s efforts to assist Applicant with this phrase. Applicant has considered the language suggested by the Examiner and has amended the claims above, in view of the suggested language with some modifications, which Applicant believes to be helpful in improving clarity. Thus, Claim 1, step b), as amended, recites:

“b) dispensing one distinguishable population of said N populations of carrier beads into a separate, corresponding one of N different reaction vessels, so that said one of N different reaction vessels contains one of said N populations, and performing said dispensing for each population of said N populations.”

Applicant believes that the adjusted language is supported in the specification at pages 10-11, and by Fig. 1, and that a reading of claim 1, step b), as amended above, in light of the specification, clarifies Applicant’s intended meaning.

Similarly, the above rejection as applied to claim 1, step c), and the phrase “dispensing each of the N samples into a separate corresponding one of said N different reaction vessels” has been addressed by amendment. Claim 1, step c), as amended, recites

“c) dispensing one of said N samples into a separate, corresponding one of N different reaction vessels, so that said one of N different reaction vessels contains one of said N samples and one of said N populations, and performing said dispensing for each sample of said N samples.”

Applicant believes that the adjusted language is supported in the specification at pages 10-11, and Fig. 1, and that a reading of claim 1, step c), as amended above, in light of the specification, clarifies Applicant's intended meaning.

Regarding the above rejection as applied to claim 1, step d), with respect to what is viewed by the Examiner as incomplete and confusing language, Applicant points out that step “d)” has been amended above. Step “d)” now makes clear that a fluid medium (supported at page 5, lines 1-11) is provided in each reaction vessel along with “additional reagents”. The “additional reagents” are in addition to the reagent that is bound to the carrier bead, as now recited in claim 1, step “a)” as amended. Applicant submits that the presence of additional reagents is supported in the specification in the descriptions of common high-throughput assay applications at pages 7-9, wherein various types of materials that can be included in such assays, are discussed.

Claim 1, step “d)” as amended also makes clear that the “signal moiety” present in each reaction vessel, is carried by either the reagent bound to the bead or by one of the additional reagents. Applicant submits that step “d)” as amended above, provides further

clarity regarding the relationships between the additional reagents and compound to be tested and the carrier beads.

As for specific relationships between particular reagents and analytes and signal moieties, Applicant submits that such relationships vary based on the particular application desired. Therefore, Applicant respectfully traverses this portion of the rejection for the reasons set forth below.

Applicant again asserts that claim terms are not analyzed in a vacuum, but always in light of the specification to which the claims are attached. In this case Applicant points out that the specification at pages 7-15 discusses two types of assays commonly used in high-throughput screening applications, specific embodiments of the invention with reference to the figures and an example. Applicant submits that the specification provides ample guidance to one of ordinary skill in the art to recognize the various structural and functional relationships between the terms such as: reagents, carrier beads, compound to be tested, and samples. Moreover, it is apparent from the specification that the Applicant's invention does not reside in one or more specific reagents, antibodies, antigens, labels or signals. Rather, Applicant's method is adaptable to a variety of assay applications. Applicant submits that a reading of the claims in light of the specification makes evident to one of ordinary skill in the art the possible structural and functional relationships of the terms in question, within the scope of the claims.

Regarding the above rejection as applied to claim 1 and the term "an assay",

Applicant respectfully requests that the Examiner permit the use of this term. Applicant points out the exact type of assay performed will depend upon the particular application of the inventive method. However, Applicant submits that “assay” is a well-known term of art and that one of ordinary skill in the art would readily understand the term to mean for example, an analysis, measurement, evaluation or detection. Thus, Applicant maintains that the term is, in fact, definite. Applicant further points out that the objectionable phrase “the assay medium” no longer appears in claim 1, as amended above. Thus, the basis for the above rejection with respect to this term has been eliminated.

Portions of claim 1 formerly covered in step “d)” now appear in step “f)” of claim 1 as amended above. Step “f)” now recites:

f) analyzing the mixture by flow cytometry

wherein

- i) measurement of said signal moiety indicates at least one of the following:
presence or absence of said compound to be tested, concentration of said
compound to be tested, and biological activity of said compound to be
tested;
and*
- ii) measurement of said detectable label indicates the sample containing the
compound to be tested.*

Applicant submits that the Examiner's objection to the earlier language that had appeared in step "f)" referring to "analysis by flow cytometry, to assay the signal moiety" has been eliminated by the deletion of the phrase. Applicant gratefully acknowledges the Examiner's suggestions for clarification. Applicant points out that the amended language of step "f)" now refers to "analyzing the mixture by flow cytometry" and "measurement of said signal moiety" or "said detectable label" to provide desired indications. Applicant submits that concept of measurement of the signal moiety to provide the desired indication, is supported in the specification at page 15 in the Example. The concept of measurement of the detectable label is supported in the specification at page 10, lines 27-30.

Regarding the above rejection as applied to claims 2, 4, 6 and 10, Applicants respectfully points out that claims 2, 4 and 10 have been cancelled above. Claim 6, has been amended above to refer specifically to "the reagent that is bound to said carrier bead." Therefore, Applicant submits that the relationship between "a reagent" in claim 6 and the reagents of claim 1, step "d)" is now clear. Thus, the basis for the above rejection as applied to claims 2, 4, 10 and 6 has been eliminated.

Regarding the above rejection as applied to claim 9, with respect to the term "the signal moiety is a fluorescent dye" the Examiner assert the term is not distinct from the "fluorescent dye" of claims 1, [2 now cancelled] and 7. In response, Applicant again points out (as was discussed at page 13 of Applicant's previous response) that the "fluorescent dye" of claim 9 refers to the signal moiety, as introduced in claim 1, step

“d)” and as discussed at pages 4-5 of the specification. The signal moiety is not the same as the “label” introduced in claim 1, step “a)” as amended and also appearing in claim 7. Applicant points out that the term “fluorescent dye” does not even appear in claims 1 [or 2] and that the “fluorescent dye” of claim 7 refers to the “detectable label” on the carrier beads of claim 1, step “a)”. Thus, the “fluorescent dye” of claim 7 refers to a different element (the label) than does the “fluorescent dye” in claim 9, which refers to the “signal moiety” of claim 1, step “d)”. Therefore, the distinction is apparent and Applicant respectfully submits that claim 9 is definite.

Regarding the above rejection as applied to claim 11 with respect to the terms “identical” and “substantially identical”, Applicant submits that one of ordinary skill in the art could readily understand, determine or make carrier beads pre-coated with identical reagent at substantially identical concentration for purposes of conducting an assay. Therefore, Applicant submits that these terms are, in fact, definite. With respect to the term “additional”, Applicant submits as discussed above, that the “additional reagents” are in addition to the reagent that is bound to the carrier bead, as now recited in claim 1, step “a)” as amended. Applicant submits that the presence of additional reagents is supported in the specification in the descriptions of common high-throughput assay applications at pages 7-9, wherein various types of materials that can be included in such assays, are discussed. Therefore, the meaning of additional reagents is apparent in relation to the reagent bound to the carrier bead. Thus, Applicant respectfully submits that claim 11 is definite. In view of the amendments and comments above, Applicant

respectfully requests that the above rejections under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

35 U.S.C. § 102(e) REJECTION OF CLAIMS 1-7, 9, & 10

Claims 1-7, 9 and 10 are rejected under 35, U.S.C. § 102(e) as anticipated by Yamashita et al., US 6,210,900 (hereinafter “Yamashita”) for reasons of record. The Examiner asserts that Yamashita, discloses Applicants’ method and directs Applicant’ attention to the “Summary”, col. 3, lines 38-55, col. 4, lines 16-37, 38-49 and col. 13, lines 1-7 of the reference. Applicant respectfully traverses this rejection for the reasons set forth below.

Applicant wishes to reiterate the previous response to the above rejection and therefore, has reproduced the previous response below, for the Examiner’s convenience. However, first, Applicant now responds to the comments in the Examiner’s “Response to Arguments” at page 10 of the Office Action, paragraph 8, at subparagraph “A”).

The Examiner asserts that the rejected claims “do not exclude that the compounds are coupled to the beads” that the preamble (of claim 1) recites “only that the samples ‘contain’ a compound to be tested” and that “‘the addition of samples containing a compound’ is not recited as a feature or limitation or method step.”

In response, Applicant concedes that claim 1 does not expressly exclude that the compound to be tested is coupled to the identifiable beads, however, such is apparent from the construction of the method steps of the claim. A review of claim 1, reveals that in step “b)” carrier beads are dispensed into reaction vessels. Later, at step “c)” samples containing the compound to be tested are dispensed into reactions vessels. Clearly, the identifiable beads and the compound to be tested cannot be coupled together because, they are introduced into the reaction vessel at different points and in different steps of the claimed method. Although, claim 1 does not expressly recite “the addition of samples containing a compound” as asserted above, the “samples” added in step “c)” are clearly defined in line 2 of the claim as “containing the . . . compound to be tested.” Thus, addition of the “samples” equals addition of samples containing the compound to be tested and is clearly an element of the claim. The disclosure of Yamashita requires analysis of compounds synthesized on the surface of the beads.

Therefore, Applicants submit that the currently pending claims cannot be anticipated by Yamashita, because an element of Applicant’s claimed method is not disclosed by Yamashita. Thus, Applicant respectfully requests that the above rejection be withdrawn.

Previous Response to the above Rejection

Yamashita discloses the use of pre-encoded beads generated by a combinatorial labeling process as supports for combinatorial synthesis of compounds on the surface of

the beads. The identity of the compounds on the beads can subsequently be determined by examination of the beads' identity.

Yamashita does not teach the use of a method with pre-existing compounds which are not coupled to beads. Consequently, Yamashita does not disclose the addition of "samples" containing a compound to be tested as instantly claimed. The method of Yamashita is not compatible with use of diverse libraries of compounds and/or compounds which are not compatible with attachment to beads. Additionally, the method is not suitable of use in analyses that are not compatible with an analyte attached to beads. Therefore, Applicants submit that the currently pending claims cannot be anticipated by Yamashita, because an element of Applicant's claimed method is not disclosed by Yamashita. Thus, Applicant respectfully requests that the above rejection be withdrawn.

35 U.S.C. § 102(e) REJECTION OF CLAIMS 1-2, 4, 6-7 & 9-10

Claims 1-2, 4, 6-7 and 9-10 are rejected under 35, U.S.C. § 102(e) as anticipated by Chandler et al., US 5,981,180 (hereinafter "Chandler") for reasons of record. Applicant respectfully traverses this rejection for the reasons set forth below.

Applicant wishes to reiterate the previous response to the above rejection and therefore, has reproduced the previous response below, for the Examiner's convenience.

However, first, Applicant now responds to the comments in the Examiner's "Response to Arguments" at pages 10-11 of the Office Action, paragraph 8, at subparagraph "B)".

The Examiner asserts that Applicant is not clear or specific regarding what is encompassed by the term "sample", which the Examiner asserts reads on "N analyte samples." In response, Applicant points out that claim 1 has been limited above to recite "said samples each containing a single compound to be tested." In view of this amendment, Applicant submits that it is now clear that only one compound per sample, is the subject analyte of the single assay performed in the claimed method. Therefore, Applicant believes that the term sample or samples, as recited in the instant claims clearly does not read on "N analyte samples" or the Chandler disclosure of one sample, multiple analytes and multiple tests.

Applicant further points out that claim 1, has been amended above to incorporate the limitations of original claim 10 (now cancelled) and make clear that the same reagents are added to all reaction vessels. Thus, the concept of many samples in a single assay is now more readily apparent.

The Examiner further asserts that the instant claims do not recite " use of encoded beads to identify a number of different samples for processing in the same assay." Applicant notes that the exact language quoted above and used by way of explanation in Applicant's previous response, may not appear verbatim in the instant claims. However, Applicant submits that the language of instant claim 1 makes clear that multiple samples

are processed in one assay and are individually identifiable. For example, claim 1, step “f), ii)” recites that “said detectable label indicates the sample containing said compound to be tested.” Therefore, Applicant points out that it is clear from the language of claim 1 that encoded beads are used to identify a number of different samples in one assay, even if these exact word do not appear in the claim.

Additionally, Applicant once again emphasizes that Chandler does not disclose multiple samples in a single assay whereas, Applicant’s claims clearly do. Therefore, Applicant submits that the currently pending claims cannot be anticipated by Chandler, because an element of Applicant’s claimed method is not disclosed by Chandler. Thus, Applicant respectfully requests that the above rejection be withdrawn.

Previous Response to the above Rejection

The Examiner asserts that Chandler, discloses Applicants’ method by pointing out that the Chandler method employs distinguishable populations of beads, flow cytometry and can be directed to multiply analytes. The Examiner directs Applicant’ attention to col. 3, lines 65 to col. 4, and col. 7, lines 25-61, and lines 63 to col. [6] 8, line 9 of the reference. Applicants respectfully traverse this rejection for the reasons set forth below.

Applicants note that their main claim 1, recites the element or limitation of “assaying N samples” and that the term “N samples” also appears in step “c)”, of the claim. “N” is defined in the last line of instant claim 1 as “greater than or equal to 2.”

This limitation is also present in claims 2, 4, 6, 7, 9 & 10, by virtue of their direct or indirect dependence from claim 1. Applicants respectfully submit that Chandler fails to disclose this same limitation as instantly claimed.

Chandler discloses a multiplexed assay of N analytes in a single sample using N populations of beads each coated with a different reactant, or a different concentration of the same reactant. Where different bead populations carry different concentrations of the same reactant, these beads are used in combination with further bead sets coated with different reactants in analysis of a single sample (see column 5, lines 38-45).

Clearly, Chandler discloses assaying multiple analytes in a single sample, as is set forth in the “Summary of the Invention” for the reference. Chandler does not disclose the use of encoded beads to identify different samples for processing in the same assay. Therefore, Applicants submit that claims 1-2, 4, 6-7 and 9-10 cannot be anticipated by Chandler because, an element of Applicant’s claimed method, is not disclosed by Chandler. Thus, Applicant respectfully requests that the above rejection be withdrawn.

35 U.S.C. § 102(e) REJECTION OF CLAIMS 1-10

Claims 1-10 are rejected under 35, U.S.C. § 102(e) as anticipated by Dower et al., US 6,165,717 (hereinafter “Dower”) for reasons of record. Applicant respectfully traverses this rejection for the reasons set forth below.

Applicant wishes to reiterate the previous response to the above rejection and therefore, has reproduced the previous response below, for the Examiner's convenience. However, first, Applicant now responds to the comments in the Examiner's "Response to Arguments" at pages 11-12 of the Office Action, paragraph 8, at subparagraph "C)". The Examiner asserts that the instant claims as recited, do not exclude that the compounds are coupled to beads.

In response, Applicants submits that, as discussed above, a review of claim 1, reveals that in step "b)" carrier beads are dispensed into reaction vessels. Later, at step "c)" samples containing the compound to be tested are dispensed into reactions vessels. Clearly, the identifiable beads and the compound to be tested cannot be coupled together because, they are introduced into the reaction vessel at different points and in different steps of the claimed method.

The Examiner further asserts that the instant claims do not recite " use of encoded beads to identify a number of different samples for processing in the same assay." In response, Applicant points out that as discussed above, the language of instant claim 1 makes clear that multiple samples are processed in one assay and are individually identifiable. For example, claim 1, step "f), ii)" recites that "said detectable label indicates the sample containing said compound to be tested." Therefore, Applicant points out that it is clear from the language of claim 1 that encoded beads are used to identify a number of different samples in one assay, even if these exact word do not appear.

In view of the above comments, Applicant submits that the currently pending claims cannot be anticipated by Dower, because an element of Applicant's claimed method is not disclosed by Dower. Thus, Applicant respectfully requests that the above rejection be withdrawn.

Previous Response to the above Rejection

The Examiner asserts that Dower, discloses Applicants' method by pointing out that the Dower method employs distinguishable populations of beads, flow cytometry and that the beads can be coated with ligands having an affinity for different multiple compounds. The Examiner directs Applicant's attention to col. 2, lines 64 to col. 3, line 21, col. 4, lines 26-38 and col. 8, lines 35-50, and columns 9-10 of the reference. Applicants respectfully traverse this rejection for the reasons set forth below.

As discussed above, Applicants point out that their main claim 1, recites elements or limitations such as "dispensing . . . N samples into separate corresponding . . . vessels" and such samples contain "a compound to be tested" as defined at the top of claim 1. Such limitations are also present in claims 2-10, by virtue of their direct or indirect dependence from claim 1. Applicants respectfully submit that Dower fails to disclose these limitations as instantly claimed.

Applicant's review of the Dower reference reveals that it discloses the use of beads in split and pool combinatorial synthesis where each addition to molecules being

synthesized is accompanied by attachment of a tag identifying the addition. The resulting combinatorial library can be screened and the structure of active compounds elucidated from the tags.

Dower does not disclose the use of the method with pre-existing compounds that are not coupled to beads. The method of Dower is not compatible with use of diverse libraries of compounds and /or compounds which are not compatible with attachment to beads. Additionally, the Dower method is not suitable for use in analyses that are not compatible with an analyte attached to beads. Dower does not disclose the use of encoded beads to identify a number of different samples for processing in the same assay. Therefore, Applicants submit that claims 2-10 cannot be anticipated by Dower because, an element of Applicant's claimed method, is disclosed by Dower. Thus, Applicant respectfully requests that the above rejection be withdrawn.

PARAGRAPH "D", OF THE EXAMINER'S RESPONSE TO ARGUMENTS

In the Examiner's "Response to Arguments" at page 12 of the Office Action, paragraph 8, under subparagraph "D)", the Examiner appears to direct the Applicant to a key point in the Examiner's reasoning for the prior art rejections. The Examiner asserts that the recited claims do not distinctly define what is encompassed by "N samples" and states that Applicant does not exclude that each of the N samples may contain multiple analytes.

In response, Applicant respectfully points out that the recitation of “N samples” in claim 1, has been amended above to further clarify its meaning. Claim 1, line 2, now sets forth that each of said N samples contains “a single compound to be tested.” Applicant submits that the above amendment clarifies that each of the subject samples contains “a single compound to be tested” in the single assay performed on all N samples. In view of the foregoing amendment, Applicant respectfully points out that there is now no doubt that the “N samples” of the instant claims, do not contain multiple analytes in the context of the assay performed. Therefore, Applicant respectfully submits that the claimed invention is patentably distinct from the prior art cited. Applicant’s method is an advance over the prior art in that it permits parallel processing of multiple samples through detection instrumentation that previously could be used only in a serial fashion. Thus, Applicant respectfully requests that the prior art rejections be reconsidered and withdrawn.

35 U.S.C. § 103(a) REJECTION OF CLAIMS 8 & 11

Claims 8 and 11 are rejected under 35, U.S.C. § 103(a) as being unpatentable over Yamashita in view of Mandecki, US 5,641,634 (hereinafter “Mandecki”) for reasons of record. Before addressing the above rejection as applied to specific claims, Applicant first wishes to summarize the invention.

The instant invention teaches the use of encoded particles to permit parallel processing of many samples in a single analysis by flow cytometry. Encoded particles

(distinguishable bead populations) are added to multiple assay vessels, each vessel ultimately containing identical reagents to perform the same assay on all of the samples. Addition of the sample containing the compound to be tested (the analyte) to each assay vessel causes the partitioning of a signal between the bead population and the fluid medium in each vessel. Consequently, following pooling of samples and parallel analysis, the assay signal associated with each bead population can be determined and assay signals assigned to assay vessels and compound tested. This method is an advance over prior art methods in that it permits parallel processing of multiple samples through detection instrumentation that previously could be used only in a serial fashion.

In view of the above remarks, Applicant wishes to reiterate the previous response and therefore, has reproduced the previous response below for the Examiner's convenience. However, first, Applicant now responds to the comments in the Examiner's "Response to Arguments" at pages 12-13 of the Office Action, paragraph 8, at subparagraph "E)". The Examiner asserts that the instant claims as recited, do not exclude that the compounds are coupled to beads.

In response, Applicants submits that, as discussed above, a review of claim 1, reveals that in step "b)" carrier beads are dispensed into reaction vessels. Later, at step "c)" samples containing the compound to be tested are dispensed into reactions vessels. Clearly, the identifiable beads and the compound to be tested cannot be coupled together because, they are introduced into the reaction vessel at different points and in different steps of the claimed method.

In view of the above deficiencies of the cited references alone or in combination, the presently claimed invention is patentably nonobvious over the prior art. Thus, Applicant respectfully requests that the above rejection be withdrawn.

Previous Response to the above Rejection

In applying the above rejection to claims 8 and 11, the Examiner notes that Yamashita fails to disclose bead population that are electronically labeled and also, fails to disclose a kit, as instantly claimed. The Examiner then cites Mandecki as disclosing a multiplex assay using electronically encoded carrier beads and also, disclosing a kit for detecting compounds in samples using carrier beads, assay vessels and coated labeled reagent. Continuing, the Examiner asserts that it would have been obvious to one of ordinary skill in the art to electronically encode populations of beads as disclosed by Mandecki, in the method of Yamashita because, Mandecki discloses its applicability in multiplex assays. Further, the Examiner states that one of ordinary skill in the art would have been motivated to combine the teachings of Yamashita and Mandecki because, Mandecki disclosed the advantage thereof, in further detecting and differentiating increased numbers of analytes simultaneously in assays. Concluding, the Examiner states that it would have been obvious to one of ordinary skill in the art to incorporate the reagents, labels and vessels taught by Yamashita into a kit such as in the disclosure of Mandecki because, of recognized advantages of convenience and economy. Applicants respectfully traverse this rejection for the reasons set forth below.

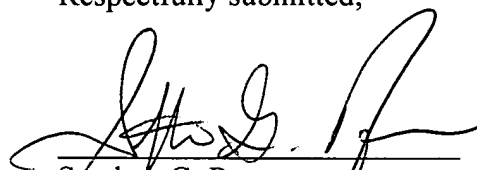
As discussed above, in connection with the rejections under 35 U.S.C. § 102, the Yamashita reference does not teach Applicant's inventive method as now claimed. Yamashita does not teach the use of a method with pre-existing compounds that are not coupled to beads. Additionally, Yamashita does not teach the addition of multiple samples containing a compound to be tested as instantly claimed. These limitations are also present in claims 8 and 11, by virtue of their dependence from claim 1.

The above deficiencies of the Yamashita reference are not remedied by Mandecki alone or in combination with Yamashita. Mandecki does not provide any teachings regarding the addition of multiple samples containing a compound to be tested. Consequently, the Examiner has not established a prima facie case of obviousness, with respect to the method as now claimed. In view of the above deficiencies of the cited references alone or in combination, the presently claimed invention is patentably nonobvious over the prior art.

In view of the above deficiencies of the cited references alone or in combination, the presently claimed invention is patentably nonobvious over the prior art. Thus, it is respectfully requested that the above rejection be withdrawn.

Early and favorable action is earnestly solicited.

Respectfully submitted,

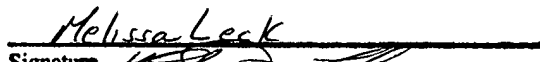


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D.C. 20231, on Dec 02.



Signature
Date December 2, 2000

Claims (marked up version showing amendments)

1. (twice amended) A method for assaying N samples, wherein N is greater than or equal to 2, said samples each containing a single compound to be tested, said method comprising:
 - a) providing N populations of carrier beads wherein the carrier beads of each population [are distinguishable]comprise a detectable label for distinguishing the carrier beads of each population from the carrier beads of every other population,
and
a reagent bound thereto,
said reagent being the same for all of said carrier beads and for all of said N populations;
 - b) dispensing [each]one distinguishable population of said N populations of carrier beads into a separate, corresponding one of N different reaction vessels, so that said one of N different reaction vessels contains one of said N populations, and
performing said dispensing for each population of said N populations;
 - c) dispensing [each] one of said N samples into a separate, corresponding one of said N different reaction vessels, so that said one of N different reaction vessels contains one of said N samples and one of said N populations, and
performing said dispensing for each sample of said N samples;

- d) providing in a fluid medium, in each of said N different reaction vessels, additional reagents for performing an assay [whereby]and wherein the same said additional reagents are provided in all of said N different reaction vessels and wherein one of said additional reagents or said reagent bound to said carrier bead, carries a signal moiety that is partitioned between said carrier beads and said fluid medium during said assay, in each one of said N different reaction vessels [and the assay medium, indicating at least one of the following: the presence or absence of the compound to be tested, the concentration of the compound to be tested, and the biological activity of the compound to be tested]and performing said assay on all of said N different reaction vessels;
- e) combining the contents of said N different reaction vessels [into]to form a mixture, and
- f) [subjecting]analyzing the mixture [to analysis]by flow cytometry[, to the signal moiety from each of a sequence of individual beads;]

wherein[N is greater than or equal to 2]

- i) measurement of said signal moiety indicates at least one of the following: presence or absence of said compound to be tested, concentration of said compound to be tested, and biological activity of said compound to be tested;

and

- ii) measurement of said detectable label indicates the sample containing said compound to be tested.

6. (three times amended) The method of claim 1, wherein [a]the reagent that is bound to said carrier bead, of the reagents recited in step d), is provided on said carrier beads, which are pre-coated with said reagent for performing the assay.
7. (three times amended) The method of claim [2]1, wherein said detectable label comprises at least one fluorescent dye.
8. (three times amended) The method of claim [2]1, wherein said detectable label comprises an electronic label.
11. (twice amended) A kit for assaying, according to the method of claim 1, N samples, each of said samples containing [one or more]a single compound to be tested, said kit comprising:

N populations of carrier beads wherein the carrier beads of each population are distinguishable from the carrier beads of every other population, and wherein all the beads are pre-coated with identical reagent at a substantially identical surface concentration for performing the assay;

and

a supply of additional reagents for performing the assay,

wherein N is [at least]greater than or equal to 2.

Claims (clean version encompassing amendments)

- Sub 101
1. (twice amended) A method for assaying N samples, wherein N is greater than or equal to 2, said samples each containing a single compound to be tested, said method comprising:
- a) providing N populations of carrier beads wherein the carrier beads of each population comprise a detectable label for distinguishing the carrier beads of each population from the carrier beads of every other population, and
a reagent bound thereto,
said reagent being the same for all of said carrier beads and for all of said N populations;
 - b) dispensing one distinguishable population of said N populations of carrier beads into a separate, corresponding one of N different reaction vessels, so that said one of N different reaction vessels contains one of said N populations, and
performing said dispensing for each population of said N populations;
 - c) dispensing one of said N samples into a separate, corresponding one of said N different reaction vessels, so that said one of N different reaction vessels contains one of said N samples and one of said N populations, and
performing said dispensing for each sample of said N samples;
 - d) providing in a fluid medium, in each of said N different reaction
- C1

Sub P1
cont.

vessels, additional reagents for performing an assay and wherein the same said additional reagents are provided in all of said N different reaction vessels and wherein one of said additional reagents or said reagent bound to said carrier bead, carries a signal moiety that is partitioned between said carrier beads and said fluid medium during said assay, in each one of said N different reaction vessels and

performing said assay on all of said N different reaction vessels;

- e) combining the contents of said N different reaction vessels to form a mixture, and
- f) analyzing the mixture by flow cytometry

wherein

- i) measurement of said signal moiety indicates at least one of the following: presence or absence of said compound to be tested, concentration of said compound to be tested, and biological activity of said compound to be tested;

and

- ii) measurement of said detectable label indicates the sample containing said compound to be tested.

C1
cont.

3. (twice amended) The method of claim 1, wherein N is 80 – 100,000.

5. (twice amended) The method of claim 1, wherein N is from 80 to 4000.

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6. (three times amended) The method of claim 1, wherein the reagent that is bound to said carrier bead, of the reagents recited in step d), is provided on said carrier beads, which are pre-coated with said reagent for performing the assay.

C4

7. (three times amended) The method of claim 1, wherein said detectable label comprises at least one fluorescent dye.

8. (three times amended) The method of claim 1, wherein said detectable label comprises an electronic label.

C5

9. (twice amended) The method of claim 1, wherein said signal moiety is a fluorescent dye.

11. (twice amended) A kit for assaying, according to the method of claim 1, N samples, each of said samples containing a single compound to be tested, said kit comprising:

C6

N populations of carrier beads wherein the carrier beads of each population are distinguishable from the carrier beads of every other population, and wherein all the beads are pre-coated with identical reagent at a substantially identical surface concentration for performing the assay;

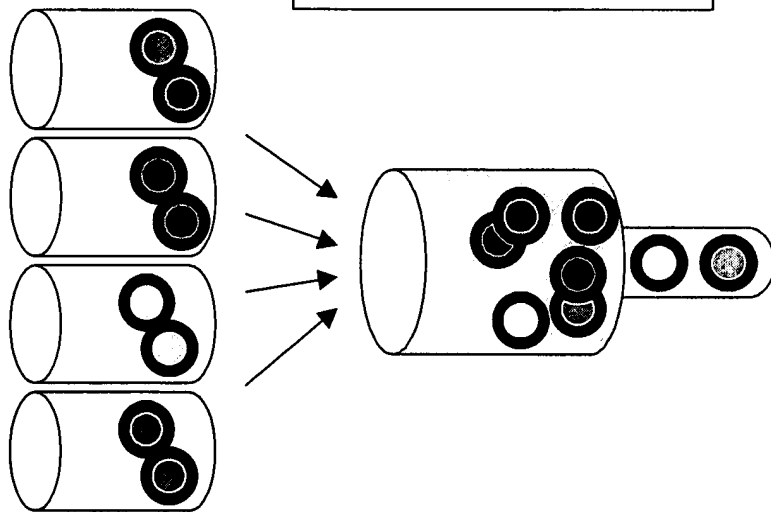
and

a supply of additional reagents for performing the assay,

wherein N is greater than or equal to 2.

Invention

N samples containing one analyte are separately mixed with 1 bead population selected from N distinguishable bead populations, each bead population being coated with the same reagent for binding the one analyte



Prior Art

One sample containing N analytes is combined with N distinguishable bead populations, each bead population being coated with a different reagent for binding one of the N analytes

